

REMARKS

Upon entry of the amendment, claims 1, 2, and 41-47 will be pending in the application. Claims 3-5 have been cancelled. Claims 46 and 47 have been amended. Support for the amendments may be found throughout the specification and claims as originally filed. See, for instance, paragraph 59. No new matter is added.

As no new matter has been added, entry of the above amendments is respectfully requested. Applicants reserve the right to pursue canceled subject matter in one or more continuing applications.

Rejection under 35 § USC 112, second paragraph

Claim 47 is rejected as indefinite. The rejection is traversed to the extent it is applied to the claims as amended.

Claim 47 as amended requires that the device of claim 46 further comprise a water-impermeable material. Claim 46, in turn, is amended to require that each pad in the plurality of distinct carrier pads in the device of claim 1 comprises a permeable material. It is submitted that claim 47 as amended is therefore not indefinite. Applicants request reconsideration and withdrawal of the rejection.

Rejections under 35 USC 102(e)/103

Claims 1-2 and 41-47 are rejected as anticipated by, or in the alternative as obvious, over Buechler (US2002/0086436) ("Buechler"). The rejection is traversed.

An element of claim 1, from which depends claim 2, is, *inter alia*, a carrier formed of a permeable material for conducting flow of liquid sample suspected of containing an analyte of

interest. Another element recited in claim 1 is a sample deposition system that delivers sample onto the carrier as a band that is essentially linear and transverse to the path of sample flow.

The examiner asserts that Buechler in paragraph 135 describes a device with a carrier formed of a permeable material. The Applicants disagree and contend that the Office is mischaracterizing the cited art. Specifically, the Applicants submit that to the extent that Buechler discloses a permeable material, such permeable material is not present on a carrier as claimed by the Applicant's, but instead is present on a second device, such as a sample delivery device, which device is used in conjunction with a reaction chamber (paragraphs 134 and 135, emphasis added):

[0134] One skilled in the art can appreciate that all formats of immunoassays or nucleic acid assays which require a separation step of free and bound conjugates or the separation of free of bound reagents which subsequently leads to the ability to detect a signal can utilize the inventive features of the diagnostic element. One skilled in the art can also recognize that the inventive elements of this invention, namely, the fingers, the sample reaction barrier, the reaction chamber, the time gate, the diagnostic element, the fluid control means and the used reagent reservoir can be used separately or in various combinations and in conjunction with other devices not described here. Furthermore, textured surfaces, such as described herein, can be utilized in one or more regions of the device to facilitate placement of a uniform layer of dried reagent in the area, or to modify fluid flow characteristics through the region. In addition, hydrophobic zones can be placed in a region of the device to modify fluid flow characteristics in the region. As appreciated by one of ordinary skill in the art, features disclosed herein can be utilized in various combinations in the preparation and use of assay devices.

[0135] For example, **the sample reaction barrier with fingers and the reaction chamber can be used in conjunction with devices incorporating porous members**, such as membranes to deliver precise volumes of reagents to the porous member. The time gate can also be incorporated into the aforementioned devices or the time gate may be used alone in conjunction with devices incorporating porous members. The fluid control means can also be used in devices incorporating porous members to control the rate of flow of reagents through the porous member. In the context of performance of assays in accordance with the invention, channels can exist such as the distance between opposing walls of a particular region, e.g., between the lid and the base; or the distance between adjacent texture structures. Accordingly, when a ligand receptor is immobilized on a device surface, a ligand of interest in a sample can diffuse across the width of a channel to bind with its receptor.

Accordingly, Buechler fails to describe the claimed invention because it does not describe a carrier formed of a permeable material for conducting flow of a liquid sample suspected of containing an analyte of interest. Therefore, Buechler fails to anticipate the claimed invention.

Further, not only does Buechler fail to teach a carrier formed of a permeable material for conducting flow of liquid sample, Buechler actually teaches away from permeable materials such as membranes. Specifically, at paragraph 114, Buechler discloses that a disadvantage of the use of membranes is that in devices configured as dipsticks, membranes are difficult to wash, making the removal of unbound agents from the membrane difficult. Buechler goes on to disclose that an improvement of such a system is to employs a plastic surface, e.g., instead of a membrane, because the plastic surface allows for the more efficient removal of unbound or excess agents. In fact, the Applicants contend that the reason the Buechler device includes the recited reaction barriers and time gates is to control the flow of a fluid sample and yet avoid the use of a permeable membrane. Accordingly, contrary to the assertions of the Office, Buechler does in fact teach that the use of porous members, such as membranes, as carriers containing analytes are detrimental to the operation of the device. Thus, Buechler teaches away from the elements of the rejected claims, and therefore, in view of M.P.E.P. §2144.05, it is improper for the Office to use Buechler in attempting to establish a *prima facie* case of obviousness. See also: *In re Geisler*, 116 F.3d 1465, 1471, 43 USPQ2d 1362, 1366 (Fed. Cir. 1997).

Further still, Buechler fails to describe the claimed invention because it does not describe a sample deposition system that delivers sample onto the carrier as a band that is essentially linear and transverse to the path of sample flow. The Office acknowledges that Buechler fails to teach that the width of the sample is larger than the width of the detection zone. However, the

Office asserts that in view of Figure 1, this is necessarily the case. The Applicants, respectfully disagree and contend that in the Office taking this interpretation of Figure 1, the Office is completely disregarding the functioning of the sample reaction barrier, element 3 of Figure 1. As can be seen from Figure 1, the sample reaction barrier is formed as a series of grooves, which grooves are parallel, i.e., not transverse, to the flow of the sample. Thus, in view of the functioning of the reaction barrier, as depicted in Figure 1, a delivered sample would be broken into parallel grooves and would not flow as a band that is essentially linear and having a width that is generally transverse to the path of sample flow. Accordingly, the Applicants contend that Figure 1, cannot be used to support such an assumption by the Office. Therefore, Buechler fails to anticipate the claimed invention.

Additionally, a *prima facie* case of obviousness requires that “either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references.” *See MPEP 706.02(j)* citing *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one ordinary skill in the art. *See MPEP §2143.01*, citing *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385, 1396 (2007). Furthermore, a statement that modifications of the prior art to meet the claimed invention would have been “well within the ordinary skill of the art at the time the claimed invention was made” because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective

reason to combine the teachings of the references. *See* MPEP §2143.01, citing *Ex parte Levingood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993) (emphasis original).

In the instant case the examiner has provided no basis as to how the artisan would have been motivated to modify the device described in Buechler. Accordingly, the claimed invention is non-obvious over Buechler.

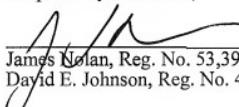
For the reasons stated herein above, the present claims are patentable over Buechler, as the cited reference fails to anticipate and/or make obvious the claimed invention.

CONCLUSION

In view of the amendments and remarks above, the Applicants respectfully submit that all of the claims are in condition for allowance. The Applicants, therefore, respectfully request reconsideration and withdrawal of the rejections. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Applicants petition for a two month extension of time for responding to the Office action (petition enclosed) with the requisite fee, authorization for a credit card payment of the filing fee is submitted herewith. No additional fees are believed to be due, however the Commissioner is authorized to credit any overpayments or charge any deficiencies to Deposit Account No. 50-0311, Reference No. 37610-523N01.

Respectfully submitted,


James N. Johnson, Reg. No. 53,393
David E. Johnson, Reg. No. 41,874

Attorney for Applicants
c/o MINTZ, LEVIN
Tel: (858) 314-1514
Fax: (858) 314-1501
Customer Number 30623

Dated: Nov. 18, 2008